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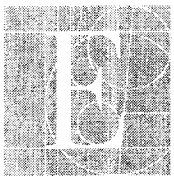
K024303
1 of 2



Edwards

510(k) Summary

1. Submitter's Name and Address:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

2. Contact:

Kevin Drisko
Senior Manager, Regulatory Affairs
Edwards Lifesciences LLC
Phone: (949) 250-2416
Fax: (949) 250-3630
E-mail: kevin_drisko@edwards.com

3. Date Prepared:

December 23, 2003

4. Device Trade Name:

Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System

5. Device Common Name:

Biliary Stent (self-expanding)

6. Device Classification Name:

Biliary Catheter (78 FGE), Class II

7. Predicate Devices:

Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System (K001843)
Cordis Precise™ Nitinol Stent Transhepatic Biliary System (K010445)
Cordis Precise™ Nitinol Stent Transhepatic Biliary System (6F) (K012993)
Cordis S.M.A.R.T.™ Control™ Nitinol Stent Transhepatic Biliary System (K021898)

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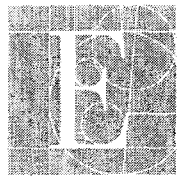

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510(k) Summary (continued)

8. Device Description:

The Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System is designed to deliver a self-expanding stent to the biliary tree via a sheathed delivery system to provide palliative treatment for malignant strictures. The Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System is comprised of the following:

- An implantable self-expanding nickel-titanium alloy (nitinol) stent. The stent is available in 6mm to 8mm diameters, and a variety of lengths.
- A 6Fr delivery system available in 75cm and 120cm usable lengths.

The Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System products are supplied sterile and are "single-use only" devices.

9. Intended Use:

The Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System is intended for use in the palliation of malignant strictures (neoplasms) in the biliary tree.

10. Technological Characteristics:

Comparisons of the new and predicate devices show that the technical characteristics such as materials, performance properties, biocompatibility, method of sterilization, and packaging are identical or substantially equivalent.

11. Performance Data:

Edwards Lifesciences completed bench testing such as deployment testing, expansion force testing, compression force testing, dimensional testing, corrosion testing, as well as tensile strength testing on applicable joints of the delivery system. The results indicate that the Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System performed in a manner substantially equivalent to the predicate devices cited in item 7 above.

12. Conclusion:

Since the Edwards LifeStent™ NT18 Self-Expanding Biliary Stent and Delivery System has the same intended use, identical material properties, similar performance properties, packaging and sterilization methods, it may be considerd substantially equivalent to the predicate devices cited in item 7 above.

Edwards Lifesciences LLC
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2003

Mr. Kevin Drisko
Senior Manager, Regulatory Affairs
Edwards Lifesciences, LLC
One Edwards Way
Irvine, California 92614

Re: K024303
Trade/Device Name: Edwards LifeStent NT18 Self-Expanding Biliary Stent and Delivery System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: April 3, 2003
Received: April 4, 2003

Dear Mr. Drisko:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K024303

Device Name: LifeStent NT18 Self-Expanding Biliary Stent and Delivery System

FDA's Statement of the Indications For Use for device:

The Edwards Lifesciences LifeStent NT18 Self-Expanding Biliary Stent and Delivery System is indicated for use in the palliative treatment of patients with malignant biliary strictures.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024303